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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/058,967	01/30/2002	Eric R. Cosman	11747-009001	4492

7590

05/26/2004

Steptoe & Johnson LLP
1330 Conn Avenue N. W.
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EXAMINER

VRETTAKOS, PETER J

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 05/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/058,967	COSMAN, ERIC R.	
	Examiner	Art Unit	
	Peter J Vrettakos	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3-24-04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Applicant has filed an amendment dated 3-24-04. Substantive amendments were made to each of the independent claims (1,11,14,17, and 28). Claims 35-37 were added.

The rejections below are nearly the same as in the first Office Action. Changes are in bold. The Response to Arguments section addresses the Amendment submitted 3-24-04.

The instant action is **final**.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1,2,3,7,9,11,14,17,19,20-22, and 24-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Panescu et al. ('267).

Independent claims 1,11,14,17

Panescu et al. (Panescu) discloses a device, amongst several embodiments, and method for tissue ablation comprising:

an elongate/tubular member (figure 15; element 22) with longitudinal passage/lumen dimensioned to pass a guide element (126),

the elongate/tubular member including an electrode (16) disposed at a distal portion of the elongate member;

a fluid channel (64) and port (44) in thermal communication with the electrode.

Note: the elongate member (22) and the electrode (16) are depicted in figure 15a as contiguous/seamless.

Dependent claims

Re: claims 2, Panescu depicts a blunt tip in figure 15a.

Re: claims 3,26, and 27, Panescu discloses fluid inlet (54) and outlet (72) ports, a fluid source (50), and injector (56) in figure 19.

Re: claims 7 and 9, Panescu discloses a flexible elongate member (col. 4:63-64).

Re: claim 19, Panescu also discloses a flexible guide wire (34, col. 5:6).

Re: claim 20, Panescu discloses a rigid stylet wire (126, col. 19:23-25) – includes a stainless steel sleeve (128).

Re: claims 21,22,24, and 31, Panescu depicts an anchor (150) in figure 15c.

Re: claim 25, Panescu depicts a generator (12) and an electrical conductor (32) in figure 2a.

Re: claims 35-37, Panescu depicts in figure 15a the fluid output port (44) at a proximal portion of the elongate member (22).

2. Claims 1-20, 22-23, 25-30, and 33-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Brucker et al. ('267).

Independent claims 1,11,14,17,28

Brucker et al. (Brucker) discloses a device (10; several embodiments) and method for tissue ablation comprising:

an elongate/tubular member (figure 1; element 16) with longitudinal passage/lumen (17) dimensioned to pass a guide element (68; col. 5:47-49),

the elongate/tubular member including an electrode (18,20) disposed at a distal portion of the elongate member;

a fluid channel (64) and port (58) in thermal communication with the electrode (see col. 5:17).

Method steps include using a guide element (30) to establish a tract;

(using embodiment in figure 12) sliding an electrode (202,204) including an elongate member (200) along **and over** the guide element (col. 7:16-18; ablation catheter in figure 6 is directly analogous to that in figure 12) **directed into the body (by needle 210)**;

and supplying high frequency energy (col. 7:23-27).

Dependent claims

Re: claims 2, Brucker depicts a blunt tip in figure 3.

Re: claims 3,26, 27, 29, and 33, Brucker discloses fluid inlet (34) and outlet (58) ports, a cooling saline source (inherent), and injector (col. 10:1-10).

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Re: claim 4, Brucker discloses a rigid elongate member (col. 2:41-44).

Re: claim 5, Brucker discloses a distal tip with a rounded contour (figure 6).

Re: claims 7 and 9, Brucker discloses a flexible elongate member (col. 2:41-44).

Re: claims 6,8, and 15, Brucker depicts an electrode (202,204) in figure 12 with a tapered contour converging with the distal opening of the elongate member.

Re: claims 10 and 16, Brucker discloses ring electrodes (col. 4:11-13).

Re: claim 12, Brucker discloses a metal tube (figure 8; 70) and insulation (polyimide tubing; col. 6:16). The electrodes represent inner metal tubing, see figure 7 and the lumen 82 could hold fluid.

Re: claim 13, Brucker discloses a plastic tubular member (col. 3:43-44) and a metallic electrode (col. 2:4-6).

Re: claims 18 and 30, Brucker discloses a needle element (col. 10:1-10).

Re: claims 19 and 20, Brucker discloses guide/stylet wires (col. 6:50-52).

Re: claims 22 and 23, Brucker discloses a movable member (66; col 5:9-11).

Re: claim 25, Brucker discloses a generator and an electrical conductor (col. 5:43-46).

Re: claim 34, Brucker discloses introducing drugs (such as chemo agents) in col. 10:10.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 21, 24, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brucker in view of Panescu.

Brucker neglects to disclose an anchor.

Panescu discloses an anchor as discussed above that could easily and obviously be inserted into the Brucker device submitted above. The motivation to do so is to anchor the device to the targeted tissue to prevent slippage during energy application.

4. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brucker in view of Nishtala et al. ('678).

Nishtala discloses a dilating element for **enlarging** a tract created in an analogous protocol to the Applicant's and Brucker's. The motivation to combine the patents would be to permit an easy and consistent means of creating a **clear** tract for passageway of surgical tools such as Brucker's.

Response to Arguments

5. Applicant's arguments filed 3-24-04 have been fully considered but they are not persuasive. Contrary to the Applicant's assertions, Panescu discloses (see figure 15) a catheter body (22) and a guide element (126) directed into tissue, and the catheter body (22) is dimensioned to pass or slide along (see double-sided arrow in figure 15a) and over the element (126). Panescu also describes a device or system for ablating tissue that includes an elongate member (22) defining a longitudinal passage or lumen having

a distal opening and proximal opening dimensioned to pass or slide over a guide element (126) directed into the tissue (see guide element extension 150 in figure 15c; col. 19:60-65).

Also contrary to the Applicant's assertions, Brucker discloses a passage (17) dimensioned to pass or slide over element (68; col. 5:47-49). Also, Brucker's embodiment in figure 12 does indeed include electrodes (202).

It is also noted that the independent claims do not claim the guide element. Therefore, a guiding element and its structural characteristics are not required in the prior art to permit a valid rejection. Instead, the independent claims only claim an elongate member.

The prior Double Patenting rejection has been obviated. The 6,506,189 patent, although has similar figures to those in the instant Application, makes no mention of device dimensions that permit passage of a guiding element.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J Vrettakos whose telephone number is 703 605 0215. The examiner can normally be reached on M-F 9-6.

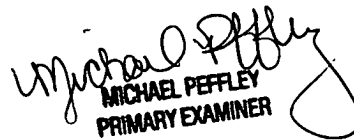
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C Dvorak can be reached on 703 308 0994. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 0858.

Pete Vrettakos
May 24, 2004



MICHAEL PEFFLEY
PRIMARY EXAMINER